ΑD					

AWARD NUMBER: W81XWH-05-1-0577

TITLE: Criterion-Based Training to Reduce Surgical Errors

PRINCIPAL INVESTIGATOR: Marvin P. Fried

CONTRACTING ORGANIZATION: Montefiore Medical Center

Bronx, NY 10467

REPORT DATE: September 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

DEDORT DOCUMENTA		Form Approved	
REPORT DOCUMENTAT	OMB No. 0704-0188		
data needed, and completing and reviewing this collection of this burden to Department of Defense, Washington Headqu	stimated to average 1 hour per response, including the time for reviewing instructions of information. Send comments regarding this burden estimate or any other aspect of arters Services, Directorate for Information Operations and Reports (0704-0188), 12 any other provision of law, no person shall be subject to any penalty for failing to com DUR FORM TO THE ABOVE ADDRESS.	this collection of information, including suggestions for reducing 15 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-	
1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED	
1 September 2009	Annual	24 Aug 2008 – 23 Aug 2009	
4. TITLE AND SUBTITLE		5a. CONTRACT NUMBER	
Criterion-Based Training to Reduce	5b. GRANT NUMBER W81XWH-05-1-0577		
		5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)		5d. PROJECT NUMBER	
Marvin P. Fried	5e. TASK NUMBER		
E-Mail: mfried@montefiore.org		5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S	S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT	
·	,	NUMBER	
Montefiore Medical Center			
Bronx, NY 10467			
9. SPONSORING / MONITORING AGENCY	NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)	
U.S. Army Medical Research and M		. ,	
Fort Detrick, Maryland 21702-5012			
·		11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATE Approved for Public Release; Distrib			
Approved for Fubility Release, Distrik	duon onimited		
13. SUPPLEMENTARY NOTES			
14. ABSTRACT			
This approach produces surgeons v for patient safety. In contrast, pilots proficiency in their MOS prior to repand the trainee is required to consis surgical simulator (the ES3) to train based training is superior to training Eight attending otolaryngologists will assessment. Subjects will complete abilities. An experimental group will control group will train by repeatedly be videotaped and objectively assess	ery. Surgical training typically lasts for a specified tivith considerably variable skill levels. Also, training and other non-medical personnel are trained to crit orting for duty. Proficiency levels are objectively estently demonstrate that level of proficiency before particular residents to criterion performance levels, a for a fixed number of trials. Twenty-four otolaryngout lestablish performance criteria and will serve as considerable a battery of validated objective tests to assess visual be trained to criterion on the simulator, and then performing the same procedure on patients, with resed for explicitly defined metrics. We hypothesize ide evidence for training on simulators before ever	on patients is becoming unacceptable eria on simulators to ensure skill tablished by experienced practitioners, progressing. We propose to use a and to investigate whether criterionology residents will serve as subjects. Emparators for infra-operative prospatial, perceptual and psychomotor erform a procedure on a patient. A no simulator training. All procedures will that prior training to established criteria	
15. SUBJECT TERMS Surgical Simulation Training to prof	iciency. Virtual reality Training. Patient Safety		
Survical Simulation. Training to brot	iciency, vinuai realliv Training, Palleni Saletv		

17. LIMITATION

OF ABSTRACT

UU

c. THIS PAGE

U

18. NUMBER

OF PAGES

6

16. SECURITY CLASSIFICATION OF:

b. ABSTRACT

U

a. REPORT

U

19a. NAME OF RESPONSIBLE PERSON

19b. TELEPHONE NUMBER (include area

USAMRMC

code)

Table of Contents

	<u>Page</u>
Introduction	4
Body	4
Key Research Accomplishments	5
Reportable Outcomes	None
Conclusion	None
References	None
Appendices	None

INTRODUCTION:

Technical abilities are highly individualistic, as shown by the wide range of ability characterizing different musicians, artists, and others. Given that the issue of creating a competent and safe surgeon is of paramount importance, we hypothesize that the objective measurement of a resident's progress is critical to both the achievement and the assessment of proficiency.

BODY:

Nine junior (postgraduate years 1, 2, and 3) Otorhinolaryngology residents were enrolled at the Montefiore Medical Center site as the subject group. All have undergone baseline skills assessment on the Endoscopic Sinus Surgery Simulator along with having performed a digitally recorded pre-training surgical procedure in the operating room. Eight residents have completed training to proficiency, indicated by achieving a score of greater than 94 on the Sinus Surgery Simulator three consecutive times, as previously determined by a panel of experts. Four of these residents have performed a digitally recorded post-training surgical procedure in the operating room and therefore have completed their participation in the study. The other resident will perform the digitally recorded post-training surgical procedure in the operating room as soon as an eligible surgery becomes available. One resident remains to be trained on the ES3 until proficiency is reached. Five remain to be recorded on their final surgical performance.

The control group is composed of nine junior Otorhinolaryngology residents from two collaborating institutions, Montefiore Medical Center and New York University Medical Center. Our efforts in establishing the control group had been extensively delayed while awaiting ORP approval for submission of an IRB to New York University Medical Center. We had originally sent the application to the ORP on February 15, 2007. The subject protocol for New York University Medical Center was resubmitted on July 29, 2008. The subject protocol for that institution was reviewed and accepted by the USAMRMC, ORP, and HRPO on July 30, 2008. Moreover, eligible cases for resident involvement are limited. Many sinus surgeries are disqualified because they do not reach our established criteria of being over 18 years of age with no previous endoscopic sinus surgeries and no obstructing pathology. Since approval of IRB submission to our collaborating institution, six of the seven junior residents at New York University Medical Center who will make up the control group had their base-line skills assessed. Two of these residents have completed all four live training OR video tapings while assisting in ESS cases and have completed their participation in the study. We will begin videotaping the live training of the four remaining residents at New York University Medical Center as soon as eligible surgeries are available. Two residents from Montefiore Medical Center also make up the control group. Both have had their base-line skills assessed. begin video taping their live training in the OR as soon as eligible surgeries become available as well.

We have videotaped the benchmark endoscopic sinus surgical procedures performed by two otolaryngology attending physicians. We plan on taping three more attending doctors shortly since this aspect of the study was also dependent on receiving ORP clearance for IRB submission.

We are also currently in the process of establishing intra-rater reliability of the expert sinus surgeons who make up the rater group. This will enable us to analyze the surgical procedure recordings as soon as the videotaping of the subject and control groups are complete.

Key Research Accomplishments:

- Completion of initial assessment by 9/9 subject group residents on ES3
- Completion of initial recording of pre-training surgical procedure by 9/9 subject group residents
- Completion of training to proficiency by 8/9 subject group residents on ES3
- Completion of final recording of post-training surgical procedure by 4/9 subject group residents
- Completion of initial assessment by 8/9 control group residents on ES3
- Completion of initial recording by 2/9 control group residents
- Completion of recorded surgical procedure by 2/5 expert Endoscopic Sinus Surgeons

Reportable Outcomes:

We do not, as of yet, have any reportable outcomes due to the delays delineated above. Anticipated time to completion is 6-9 months.

inticipated time to completion is 6-9 months.	
onclusions:	
I/A	
eferences: //A	
ppendices: I/A	
upporting Data: //A	

REPORT OF INVENTIONS AND SUBCONTRACTS Form Approved OMB No. 9000-0095 (Pursuant to "Patent Rights" Contract Clause) (See Instructions on back) Expires Jan 31, 2008 The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense. Executive Services Directorated (9000-0095). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO THE CONTRACTING OFFICER. 1 a NAME OF CONTRACTOR/SURCONTRACTOR C CONTRACT NUMBER 2 a NAME OF GOVERNMENT PRIME CONTRACTOR 3 TYPE OF REPORT /X one! US Army Medcial Research and Materials C W81XWH-05-1-0577 X a. INTERIM b. FINAL h ADDRESS Unclude ZIP Codel d AWARD DATE h ADDRESS (Include ZIP Code) d. AWARD DATE 4. REPORTING PERIOD (YYYYMMOD) (YYYYMMDD) US Army Medical Research and Material Command (YYYYMMDD) Same as 1a a. FROM 20080923 Fort Derrick, maryland 21702-5012 ь. то 20090823 SECTION I - SUBJECT INVENTIONS 5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR (If "None " so state) FLECTION TO FILE CONFIRMATORY INSTRUMENT DISCLOSURE NUMBER. PATENT APPLICATIONS (Y) OR ASSIGNMENT FORWARDED NAME(S) OF INVENTOR(S) TITLE OF INVENTION(S) PATENT APPLICATION TO CONTRACTING OFFICER (X) (Last First Middle Initial) SERIAL NUMBER OR 1) UNITED STATES (2) FOREIGN PATENT NUMBER (a) YES (b) NO (a) YES IN NO (a) YES (b) NO None f. EMPLOYER OF INVENTOR(S) NOT EMPLOYED BY CONTRACTOR/SUBCONTRACTOR a. ELECTED FOREIGN COUNTRIES IN WHICH A PATENT APPLICATION WILL BE FILED (1) (a) NAME OF INVENTOR (Last, First, Middle Initial) (2) (a) NAME OF INVENTOR (Last, First, Middle Initial) (1) TITLE OF INVENTION (2) FOREIGN COUNTRIES OF PATENT APPLICATION (b) NAME OF EMPLOYER (b) NAME OF EMPLOYER (c) ADDRESS OF EMPLOYER (Include ZIP Code) (c) ADDRESS OF EMPLOYER (Include ZIP Code) SECTION II - SUBCONTRACTS (Containing a "Patent Rights" clause) 6. SUBCONTRACTS AWARDED BY CONTRACTOR/SUBCONTRACTOR (If "None." so state) FAR "PATENT RIGHTS" SUBCONTRACT DATES (YYYYMMDD) NAME OF SUBCONTRACTOR(S) SUBCONTRACT DESCRIPTION OF WORK TO BE PERFORMED ADDRESS (Include ZIP Code) NUMBER(S) UNDER SUBCONTRACT(S) (2) ESTIMATED (1) CLAUSE (2) DATE (1) AWARD NUMBER (YYYYMM) COMPLETION None SECTION III - CERTIFICATION 7. CERTIFICATION OF REPORT BY CONTRACTOR/SUBCONTRACTOR (Not required if: (X as appropriate)) SMALL BUSINESS or NONPROFIT ORGANIZATION I certify that the reporting party has procedures for prompt identification and timely disclosure of "Subject Inventions," that such procedures have been followed and that all "Subject Inventions" have been reported. a. NAME OF AUTHORIZED CONTRACTOR/SUBCONTRACTOR b. TITLE c. SIGNATURE d. DATE SIGNED OFFICIAL (Last, First, Middle Initial)